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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,579	08/22/2000	Richard Martin Broglie	BB1334 USNA CNT1	3114

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EXAMINER

KALLIS, RUSSELL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/643,579

Applicant(s)

BROGLIE ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25,29,37,39-44 and 49-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,25,29,37,39-44 and 49-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Rejection of Claims 23, 25, 29, 37, 39-44 and 49-58 under 35 U.S.C. 112, first paragraph, written description is withdrawn in view of Applicant's amendments and arguments.

Claims 23, 25, 29, 37, 39-44 and 49-58 are pending and examined.

Claim Rejections - 35 USC § 112

Claims 23, 25, 29, 37, 39-44 and 49-58 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing of oleic acid (18:1) in plant seeds transformed with the mutant delta-12 fatty acid desaturase genes of SEQ ID NO: 3 (pZPhMCFd2) (Example 4 pages 34-39) as well as coding sequences for delta-12 fatty acid desaturases having a substitution of a Lys residue for an Asp or Glu in an His-Glu-Cys-Gly-His, His-Asp-Cys-Gly-His, or His, Asp-Cys-Ala-His amino acid region wherein the levels of oleic (18:1), linoleic 18:2) and linolenic (18:3) acid range from 72.5-78.6% for oleic acid, 6.4-10.6% for linoleic acid and 4.51-6.5% for linolenic acid respectively, does not reasonably provide enablement for a method of increasing levels of seed oleic as high as 90% recited in Claims 23 39 and 40, or seed oleic as high as 88% recited in Claims 41-42; or as low as 1% linoleic acid recited in Claims 25 and 44, and as low as 1% linolenic acid recited in Claim 43. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/06/2004. Applicant's arguments filed 4/06/2005 have been considered but are not deemed persuasive.

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Applicant asserts that the T2 generation plants are not homozygous for the mutant delta-12 desaturase and it is expected that the T3 and subsequent generations will have fatty acid levels that match the breadth of the claims (response page 14). Applicant is invited to submit a Declaration showing the fatty acid levels in seeds of T3 and subsequent generations of transformed plants.

Applicant asserts that multiple gene strategies were not necessary when antisense strategies were employed to reduce linolenic and linoleic and to increase oleic acid levels in transformed *Brassica* (response page 15). The claims are drawn to mutant delta-12 desaturase enzymes not antisense. Applicant's arguments suggest that only antisense is required to obtain the fatty acid levels in seeds set forth in the claims. Clearly, the Lightner reference shows that multiple strategies, (where the plant is a double homozygous i.e. homozygous for both the transgene and the mutation), were required for the dramatic alterations in fatty acid composition in transformed seeds that Applicant now claims.

Applicant asserts that one of ordinary skill after reading Lightner would have realized that linolenic acid levels of from 1 to 10% could have been readily attained (response page 15). Applicant is invited to point to the place in Lightner that teaches linolenic levels of 1%. Further, Applicant's assertions that there are varieties that have higher linolenic acid levels higher than Westar does not teach how to obtain a method of increasing levels of seed oleic as high as 90% recited in Claims 23 39 and 40, or seed oleic as high as 88% recited in Claims 41-42; or as low as 1% linoleic acid recited in Claims 25 and 44, and as low as 1% linolenic acid recited in Claim 43.

The teachings and examples in the specification do not reasonably provide enablement for a method of increasing levels of seed oleic as high as 90% recited in Claims 23-39 and 40, or seed oleic as high as 88% recited in Claims 41-42; or as low as 1% linoleic acid recited in Claims 25 and 44, and as low as 1% linolenic acid recited in Claim 43.

Applicant broadly claims a method for increasing oleic acid content in plant seeds by transformation with a delta-12 fatty acid desaturase coding sequence having a Asp/Glu to Lys mutation in a conserved (Ala/Gly)-His-(Asp/Glu)-Cys-Gly-His sequence and a recombinant construct effective for increasing oleic acid content when expressed in seeds comprising a coding sequence of a delta 12- fatty acid desaturase having a Asp/Glu to Lys substitution in a conserved His-(Asp/Glu)-Cys-(Gly/Ala)-His sequence that renders the desaturase non-functional.

Applicant teaches a method of increasing of oleic acid (18:1) and lowering linoleic (18:2) and linolenic acid (18:3) in seeds of *Brassica napus* (var. Westar) transformed with the mutant delta-12 fatty acid desaturase genes of SEQ ID NO: 3 (pZPhMCFd2) (Example 4 pages 34-39) wherein the levels of oleic, linoleic and linolenic acid range from 72.5-78.6% for oleic acid, 6.4-10.6% for linoleic acid and 4.51-6.5% for linolenic acid respectively.

Applicant does not teach a method of increasing levels of seed oleic, and lowering linoleic and linolenic acid resulting in ranges of above 78.6% for oleic acid (18:1), and lower than 6.4% for linoleic acid (18:2), and lower than 4.51% for linolenic acid (18:3).

The state of the art for increasing oleic acid content and decreasing linoleic and linolenic acid content in the seeds of plants by blocking the conversion of oleic acid to linoleic and linolenic acid by transformation with a mutant form of the endogenous delta 12 desaturase is unpredictable because this type of mutational inhibition or dominant negative inhibition of gene

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expression is leaky and requires multiple gene expression inhibition strategies to achieve levels of oleic acid in plant seeds such that seed oleic acid levels increase to 90% and linoleic and linolenic acid levels decrease to 1%. This is clearly made evident in a *Brassica napus* high oleic mutant homozygous for a mutant of delta 12 desaturase (IMC 129) resulting in a high seed oleic acid trait that required an additional antisense construct (158-8-1) to further inhibit delta 12 desaturase activity such that levels of seed oleic acid would increase to 90%. The data shows that seed oleic acid content in the cross of IMC 129 x 158-8-1 are higher than either parent (Lightner J.E. *et al.* U.S. Patent 6,372,965 B1, issued 2002; see column 65, Table 18; and column 66, Table 19 and lines 22-27).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified transformed plants comprising any one of a myriad of delta 12 desaturase proteins comprising a mutant delta-12 sequence having a Lys substituted for a Asp/Glu in a (Ala/Gly)-His-(Asp/Glu)-Cys-Gly-His conserved sequence to identify those polynucleotides that when transformed and expressed in plants produce plants having seeds with increased oleic acid levels as high as 90% and linoleic and linolenic acid levels as low as 1%.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites the limitation "wherein said mutation is in a Ala-His-Glu-Cys-Gly-His (SEQ ID NO: 23 amino acid region" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim, i.e. "said mutation". Further, SEQ ID NO: 23 is not recited in the Markush Group of Claim 23.

All Claims are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis PhD
July 9, 2005

RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER

Russell Kallis